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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-------------------------|--|------------|----------------------|-------------------------|------------------|--|
| 09/864,793 | 09/864,793 05/24/2001 | | Gregory Murphy | 28122.90 2880 | | |
| 27683 | 7590 | 02/14/2003 | | | | |
| HAYNES AND BOONE, LLP | | | | EXAMINER | | |
| 901 MAIN S DALLAS, T | TREET, SUITE 3100 X 75202 MATTHEWS, WILLIAM | | | | WILLIAM H | |
| | | | | ART UNIT | PAPER NUMBER | |
| | | | | 3738 | | |
| | | | | DATE MAILED: 02/14/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

| | Application No. | Applicant(s) | | | | | | |
|---|---|--|-----------------|--|--|--|--|--|
| | 09/864,793 | MURPHY ET AL. | \leq | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | | |
| | William H. Matthews (Howie) | 3738 | | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence ad | ldress ` | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 16(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timel the mailing date of this c D (35 U.S.C. § 133). | | | | | | |
| 1) Responsive to communication(s) filed on <u>05 N</u> | lovember 2002 . | | | | | | | |
| 2a) This action is FINAL . 2b) ☑ Thi | s action is non-final. | | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | | | |
| 4)⊠ Claim(s) <u>15-19 and 25-74</u> is/are pending in the | e application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | vn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6) Claim(s) 15-19,25,26,28,29,32-39,41,42,45-51, | .53-63 and 65-74 is/are rejected. | | | | | | | |
| 7)⊠ Claim(s) <u>27,30,31,40,43,44,52 and 64</u> is/are objected to. | | | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | | |
| Application Papers | | | | | | | | |
| 9)☐ The specification is objected to by the Examiner | : | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | | |
| If approved, corrected drawings are required in rep | • | | | | | | | |
| 12) The oath or declaration is objected to by the Exa | aminer. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a |)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | | |
| 1. Certified copies of the priority documents | s have been received. | | | | | | | |
| 2. Certified copies of the priority documents | s have been received in Applicati | on No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14)☐ Acknowledgment is made of a claim for domestic | c priority under 35 U.S.C. § 119(| e) (to a provisiona | l application). | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | |
| Attachment(s) | | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal | / (PTO-413) Paper No Patent Application (PT | | | | | | |
| S. Patent and Trademark Office | | | | | | | | |

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DETAILED ACTION

Inventorship

The request to correct the inventorship of this nonprovisional application under
 CFR 1.48(a) is deficient because:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted. Specifically, the submitted declaration lacks a date for one inventor.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 18,51-55,59, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al. US PN 6,162,537.

Martin et al. discloses a ventricular patch (lines 34-47 of col. 12) having a combination of fibers that are treated with radiopaque dyes before or after extrusion (see line 61 of col. 7 through line 58 of col. 8, lines 7-13 of col. 9, and line 59 of col. 9

through line 15 of col. 10). The second fiber may be polyester (lines 12-31 of col. 7) and the first component may be collagen (lines 25-41 of col. 6).

3. Claims 15,17,19,25,28,29,32,34-36,38,41,42,45,47-49,65,66,69, and 71-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt US PN 5,411,527.

Alt discloses a ventricular patch in figure 2 comprising metal thread markings or ink markings on a biocompatible surface in either a grid, parallel lines, or lines radiating from a point. See lines 42-52 of col. 10, lines 4-22 of col. 11, line 61 of col. 11 through line 2 of col. 12, lines 5-16 of col. 13, and lines 11-27 of col. 16.

4. Claims 18,19,51,53,57-61,63,65, and 69-73 are rejected under 35 U.S.C. 102(b) as anticipated by Milijasevic US PN 4,938,231.

Milijasevic discloses a ventricular patch in figures 2 and 10 having radiopaque threads (platinum or stainless steel threads) enveloped by a polyester mesh. (see lines 34-62 of col. 3 and line 45 of col. 5 through line 25 of col. 6).

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527.

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Alt discloses the use of metal threads in figure 2 and lines 34-40 of col. 11, but Alt does not disclose expressly the use of spacing set at 1cm.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use 1cm spacing because Applicant has not disclosed that using 1cm spacing provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the spacing used by Alt because both would provide sufficient visibility under fluoroscopy during implantation of the patch.

Therefore, it would have been an obvious matter of design choice to modify Alt to obtain the invention as specified in claim 16.

7. Claims 33,37,46,50,70, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527.

Alt meets the structural limitations of claims 33,37,46,50,70, and 74 as described above, but lacks the express disclosure of using platinum threads or using ion deposition to deposit radiopaque substances to the markings. However, Alt discloses in lines 42-52 of col. 10 and lines 11-27 of col. 16 that platinum-iridium wires or other metals may be used, and that polymer threads may be used that are coated with radiopaque materials. Furthermore, the particular use of ion deposition or platinum is widely known in the art of medical devices in order to provide sufficient visibility under fluoroscopy during implantation.

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Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have selected platinum as the material for the wire or to use ion deposition as a method of coating the polymer wires in order to provide sufficient visibility under fluoroscopy during implantation.

8. Claims 54,62,66, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milijasevic US PN 4,938,231.

Milijasevic discloses the use of metal threads in lines 34-62 of col. 3, but Milijasevic does not disclose expressly using radiopaque ink or ion deposition.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use radiopaque ink or ion deposition because Applicant has not disclosed that using radiopaque ink or ion deposition provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with metal threads because both provide sufficient visibility under fluoroscopy during implantation of the patch.

Therefore, it would have been an obvious matter of design choice to modify Milijasevic to obtain the invention as specified in claim 54,62,66, and 74.

9. Claims 26,39, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527 as applied in the 102(b) rejection above, and in further view of Milijasevic US PN 4,938,231.

Alt meets the structural limitations of claims 26,39, and 63 as described above, but lacks the express disclosure of the biocompatible material comprising polyester.

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Milijasevic teaches a ventricular patch enveloped by a polyester mesh in order to prevent burning of tissue during delivery of current. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Alt by using a polyester mesh, as taught by Milijasevic, for the biocompatible material in order to prevent burning of tissue during delivery of current.

10. Claims 55,56,67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milijasevic US PN 4,938,231 as applied in the 102(b) rejection above and in further view of Zhong et al. US PN 6,368,356.

Milijasevic meets the structural limitations of claims 55,56,67, and 68 as described above, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Milijasevic by using a polymer made with barium sulfate in order to provide sufficient visibility under fluoroscopy during implantation as taught by Zhong et al.

Note MPEP 2113 (Product by Process) for claims 55 and 67. The claims are not limited by the manipulations of the recited steps, only the structure implied by the steps.

11. Claim 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. US PN 6,162,537 as applied above in the 102(e) rejection, and in further view of Zhong et al. US PN 6,368,356.

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Martin et al. meets the structural limitations of claim 56 as described above by disclosing a polymer material made with a radiopaque dye or pigment, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Martin et al. by using a polymer made with barium sulfate in order to provide sufficient visibility under fluoroscopy during implantation as taught by Zhong et al.

Allowable Subject Matter

12. Claims 27,30,31,40,43,44,52, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant has stated that claim 18 was written in independent form according to Examiner's suggestion. However, the Examiner rejected claim 18 in the previous office action and never suggested an amendment that would place claim 18 in condition for allowance.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Tues-Fri 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

25th

WHM

February 10, 2003

David H. Willse Primary Examiner